CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The Center for Devices and Radiological Health (CDRH), part of the U.S. Food and Drug Administration (FDA), helps ensure that medical devices are safe and effective as authorized by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act and helps reduce unnecessary exposure to radiation from medical, occupational, and consumer products as authorized by the Radiation Control for Health and Safety Act of 1968.

Office of the Center Director (OCD)

OCD provides leadership and direction for all Center activities and is responsible for their evaluation and coordination. It provides advice and consultation on policy matters about medical device and radiological health activities to the Commissioner and other FDA officials, Congress, the Department of Health and Human Services, the Public Health Service, other government agencies, the scientific and academic community, and representatives of the regulated industry. It also supports the Equal Employment Opportunity (EEO) program and its management within the Center.

Office of Compliance (OC)

OC is the enforcement hub of CDRH with responsibility for directing and evaluating field inspections of manufacturers of medical devices and radiological health products nationally and abroad. OC advises the Center Director and other FDA officials on legal, administrative, and regulatory programs and policies. It oversees the compliance and surveillance programs of the regulated industry and conducts field tests and inspections needed for regulatory purposes. OC also evaluates industry quality control and testing programs and advises the FDA field offices and CDRH regarding legal actions, case development, and contested case assistance. OC is responsible for the Establishment Registration, Medical Device Listing, Government-wide Quality Assurance, and Bioresearch Monitoring Programs. It trains Federal and State compliance personnel and advises manufacturers about the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Office of Device Evaluation (ODE)

ODE is the office responsible for review of marketing applications from the medical device industry. It plans, conducts, and coordinates Center actions regarding the approval, denial, and withdrawal of approval to market a medical device. ODE also reviews applications to conduct investigational clinical studies of unapproved medical devices under the Investigational Devices Exemptions. The data gathered in these clinical studies supports marketing applications.

ODE reviews four types of marketing applications: Premarket Notification (or a 510(k) application), Premarket Approval (PMA), Product Development Protocol (PDP), and Humanitarian Device Exemption (HDE). Most devices are cleared for marketing through the 510(k) process; PMA applies only to the highest risk and newly developed (class III) devices. ODE coordinates Center classification activities; reviews and initiates petitions for reclassification of devices; interacts with and provides support to the advisory panels which make recommendations on FDA actions regarding selected devices; and conducts continuing review, surveillance, and medical evaluation of device labeling and clinical experience.

Office of Health and Industry Programs (OHIP)

OHIP specializes in the areas of program-based communication, education, radiological health, mammography quality, and resolution of device user problems. Its audiences include the radiological health and device industry, health professionals, consumers, CDRH staff, and foreign governments.

In support of Center programs, OHIP provides expertise in communications technology and produces national and international teleconferences and educational videos; applies human factors theory to the design and labeling of devices to reduce use errors; conducts qualitative research studies for use in Center information programs for health professionals, consumers, and industry; operates a program to implement the Mammography Quality Standards Act of 1992 and provides technical expertise in applying health physics procedures and radiation protection principles; provides technical assistance to medical device manufacturers, coordinates international activities, and provides information to consumers; develops regulations for medical devices and radiological health activities; and provides educational programs for Center employees.

Office of Science and Technology (OST)

OST, the laboratory research hub of CDRH, supports FDA's regulatory decisions with laboratory research in the areas of standards, technical consultation, forensic analysis, and applied research. It leads the development and evaluation of standards used for regulatory assessments. OST supports other Center offices when specific expertise is required for solving problems or reviewing 510(k) or PMA applications. It identifies and analyzes failures of marketed devices. OST conducts research in the areas of life, physical, and engineering sciences as they relate to the health effects of radiation and medical device technologies, e.g., studying the effects of electrical fields around consumer products on cell development. OST's research assists the regulatory programs of CDRH and FDA in anticipating the impact of technology on the use, safety, and effectiveness of regulated products.

Office of Surveillance and Biometrics (OSB)

OSB develops and implements surveillance programs to assure that marketed products are safe and effective. It is the Center's source of expertise in the biometrics sciences and provides expert statistical consultation in the evaluation of premarket device applications. OSB administers a nationwide surveillance system to monitor and evaluate the safety and effectiveness of marketed devices by analyzing adverse-event reports. In collaboration with the other Center offices, OSB directs and monitors the analysis, resolution, and development of implementation strategies for postmarket issues through the Center's *ad hoc* process and postmarket safety notifications.

Office of Systems and Management (OSM)

OSM advises the Center Director on all management issues. It plans, develops, and implements cost effective Center management policies and programs concerning financial and human resource management, contract and grants management, ethics and program integrity, committee and conference management, occupational health and safety, and facilities. OSM develops and implements the Center's long-range, strategic, and operational plans; evaluates the effectiveness of Center programs; and designs administrative, scientific, and technical information systems to support Center programs. As the Center's electronic communications hub, OSM provides computer support services to the Center and web-based information to the public. Its library provides scientific information for Center staff, and the Freedom of Information (FOI) staff responds to public requests for information.

Center for Devices and Radiological Health

Director
David W. Feigal, M.D., M.P.H.
Deputy Director for Science
Elizabeth D. Jacobson, Ph.D.
Deputy Director for Regulations and Policy
Linda S. Kahan, Esq.
Phone: 301-443-4690
Fax: 301-594-1320

Associate Director for Management & Systems
Donald J. Sauer
Phone: 301-443-8120
Fax: 301-443-8396

Assistant Director for Education & Communication
Mark H. Barnett
Phone: 301-443-6220
Fax: 301-443-2962

Office of Compliance
Lillian J. Gill, Director
Phone: 301-594-4692
Fax: 301-594-4610

Office of Science & Technology
Donald E. Marlowe, Director
Phone: 301-827-4777
Fax: 301-827-4787

Office of Device Evaluation
Vacant, Director
Phone: 301-594-2022
Fax: 301-594-2510

Office of Surveillance & Biometrics
Larry G. Kessler, Sc.D, Director
Phone: 301-594-2812
Fax: 301-594-2965

Office of Health & Industry Programs
Lireka P. Joseph, Dr.P.H., Director
Phone: 301-443-2845
Fax: 301-443-8810

Office of Systems & Management
Donald J. Sauer, Director
Phone: 301-443-8120
Fax: 301-443-4396

For additional information, call:

1-888-INFO-FDA

or visit our website at:

www.fda.gov/cdrh

September 1999

Center for Devices and Radiological Health

Promoting and Protecting the Public Health

U.S. Food and Drug Administration
9200 Corporate Boulevard, HFZ-1
Rockville, Maryland 20850